#### DEPARTMENT OF VETERANS AFFAIRS

### Justification and Approval

#### For

## Other Than Full and Open Competition

### 1. Contracting Activity: Department of Veterans Affairs, VISN 12, Great Lakes Acquisition Center

Department of Veterans Affairs, Great Lakes Acquisition Center, 5000 W National Avenue Bldg 5, Milwaukee WI 53295

This document shall serve as the Contracting Officer's "Justification for Other Than Full and Open Competition"

This Justification and Approval is applicable to Purchase Request #: 695-12-1-155-0005

### 2. Nature and/or Description of the Action Being Processed:

Justification and Approval for Other Than Full and Open Competition to execute a Firm Fixed Priced contract for the purchase of prototype models of two Prone Carts for the Research Service at the Clement J. Zablocki VAMC in Milwaukee WI. This procurement will proceed on a sole source basis with D&H Global EnterPrise LLC (D&H).

# 3. <u>Description of Supplies/Services Required to Meet the Agency's Needs:</u>

The scope of work involves the following tasks:

- 1. Fabrication of three (3) *manual* prone carts.
- 2. Fabrication of one (1) Folding frame motorized prone cart
- Send the newly fabricated Folding frame motorized prone cart to the Pittsburgh VA-HERL (Human Engineering Research Laboratory) for retesting the cart for ISO's WC-02 dynamic stability test (10 degree ramp stability test)
- 4. When ISO WC-02 dynamic stability test pass, prepare and submit a 510 K application to the FDA (Food and Drug Administration) to seek approval for marketing and commercialization of the "Folding frame motorized prone cart."

The approximate cost for this equipment and service is \$65,000.00. The estimated delivery date of this equipment is 120 days after receipt of award.

#### 4. Statutory Authority Permitting Other than Full and Open Competition:

(X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1

# 5. <u>Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):</u>

The Department of Veterans Affairs has developed, and holds the patents to, two new types of prone carts that aid in mobility of spinal cord injury patients. VACO Technology Transfer Service is in the process of negotiating an Exclusive Licensing and marketing agreement with D&H. This order represents prototype models of the patented carts that the VA anticipates will be licensed to D&H. Since the VA anticipates partnering with D&H for the production of these carts these preliminary prototype orders must go them in order to build experience with the prone cart production, and establish a rubric for future cart orders.

# 6. <u>Description of Efforts Made to ensure that offers are solicited from as many potential sources as</u> deemed practicable:

Since D&H Global EnterPrise LLC is currently involved in negotiations with VACO Technology Transfer Service in order to set up an exclusive licensing agreement for the manufacture and marketing of these prone carts, D&H is the only potential source of offers.

# 7. <u>Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:</u>

The costs estimates used as the basis of D&H's quote were provided by the Department of Veterans Affairs design team. These cost estimates were derived from those team member's past experience in assembling prototype units identical to those being procured with this contract.

# 8. <u>Description of the Market Research Conducted and the Results, or a Statement of the Reasons</u> Market Research Was Not Conducted:

VACO Technology Transfer Service completed a market study to seek a manufacturer for these devices. The survey included 16 medical device manufacturing companies. D&H Global D&H Global EnterPrise LLC was the only company found that was willing to manufacture and market these new prone carts.

# 9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

NONE

### 10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

NONE

11.	A Statement of the Action	s, if any, the Agency Ma	y Take to Remove or	Overcome any Barriers to
	Competition before Making subsequent acquisitions for the supplies or services required:			

NONE

12. <u>Requirements Certification</u>: I certify that the requirement outlined in this justification is a Bona Fide Need of the

Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

(This signature is the requestor's supervisor, fund control point official, chief of service, someone with responsibility, and accountability).

NAME Phil Cook

January 31, 2012

<u>Chief Financial Officer, Research Service, Zablocki VA Medical Center TITLE</u>

FACILITY

- 13. Approvals in accordance with FAR 6.304 This part is filled out by Contracting Staff as part of the Justification.
  - a. <u>Contracting Officer's Certification</u>: (required) I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

NAME Robert Steed

DATE

Contract S

TITLE

FACILITY

c. NCM/PCM: I certify the justification meets requirements for other than full and open competition.

NAME

- 2

Network/Program Contract Manager

NCO<sub>12</sub>